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Contents lists available at ScienceDirect

Journal of the American Pharmacists Association

journal homepage: www.japha.org

FEATURE

COVID-19 vaccine confidence project

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Throughout much of 2020 and the beginning of 2021, while coronavirus disease 2019 (COVID-19) continued to grow and spread, government and public health officials worldwide focused on the development and deployment of one or more COVID-19 vaccines as a means of ending the global pandemic. While much of the U.S. Food and Drug Administration's (FDA) attention was correctly placed on ensuring that the vaccines were safe and effective, concern was also growing within the agency that Americans, particularly those most vulnerable to COVID-19, would choose not to receive the vaccine once available.¹ Public health experts hypothesized that U.S. Government agencies had a major role in understanding and addressing the concerns of the vaccine hesitant.² FDA, in recognizing that they would need to communicate with the public about any authorized or approved vaccine, wanted to better understand those concerns and be prepared with message(s) that would respond to those concerns.

In the fall of 2020, FDA approached the Reagan-Udall Foundation for the FDA (FDA Foundation) with a request to conduct a series of listening sessions with target populations to gauge the level and nature of concern in these groups. FDA furthermore asked that the FDA Foundation develop messages that would address the questions and hesitations that these populations expressed. The FDA Foundation is a nonprofit, nongovernment organization established by Congress to advance the mission of FDA. The FDA Foundation has substantial experience in engaging with different sectors of the public and regularly organizes listening sessions with various patient groups on behalf of FDA.

Aware of such concerns and vaccine hesitancy among Americans, the FDA Foundation embarked on a project to better understand these concerns and what messages FDA might effectively use to allay those concerns. The project

involved hearing directly from key segments of the American population at the highest risk of COVID-19 and exploring with them the nature of their vaccine hesitancy. The listening sessions were not meant to capture a representative sample of Americans but rather the voices of the target populations. A final objective was to develop a set of messages that responded to their concerns. These messages would be delivered to FDA for use in their messaging.

Methods

To develop effective communications for traditionally underrepresented communities and frontline health care and retail workers, the FDA Foundation began a 4-stage process, conducted between September and November 2020. The project consisted of (1) a review and analysis of mainstream and social media; (2) listening sessions to hear directly from target populations about their concerns; (3) message development to address the concerns voiced during the listening sessions; and (4) testing and refinement of those initial messages through surveys and expert interviews, with the results of each stage feeding into the next stage. The FDA Foundation updated FDA at regular intervals and delivered a final report in December 2020, shortly before the announcement of an Emergency Use Authorization for the first COVID-19 vaccine.

Review and analysis of traditional and social media

To capture the then-common sentiments regarding a potential COVID-19 vaccine, the FDA Foundation commissioned a media analysis (H Cobb, unpublished data, 2020). This analysis was conducted by an independent researcher focusing on media coverage from May to August 2020. The review of traditional media included identifying and analyzing articles in top American newspapers as well as papers in selected markets, news magazines, national broadcast outlets, wire services, and 1 online resource (WebMD) on the topic of a COVID-19 vaccine. A number of these media organizations also conducted independent polls during the summer and fall of 2020 to ascertain Americans' sentiment around a potential COVID-19 vaccine; those poll results were included in the analysis.

To assess Americans' attitude in social media, the media analysis concentrated on 4 major sources: Facebook, Pinterest, Instagram, and Twitter. A large variety of public groups,

Funding: This project is supported by the Food and Drug Administration (FDA; grant number: 1-U01-FD-007223-01) of the U.S. Department of Health and Human Services (HHS) as part of an award of \$150,000 of federal funds (88% of the project) and by \$20,000 from nongovernmental sources (12% of the project). The contents are those of the author(s) and do not necessarily represent the official views of, nor an endorsement, by FDA, HHS, or the U.S. Government. For more information, please visit FDA.gov.

Previous presentations: Numerous presentations to various professional groups and media.

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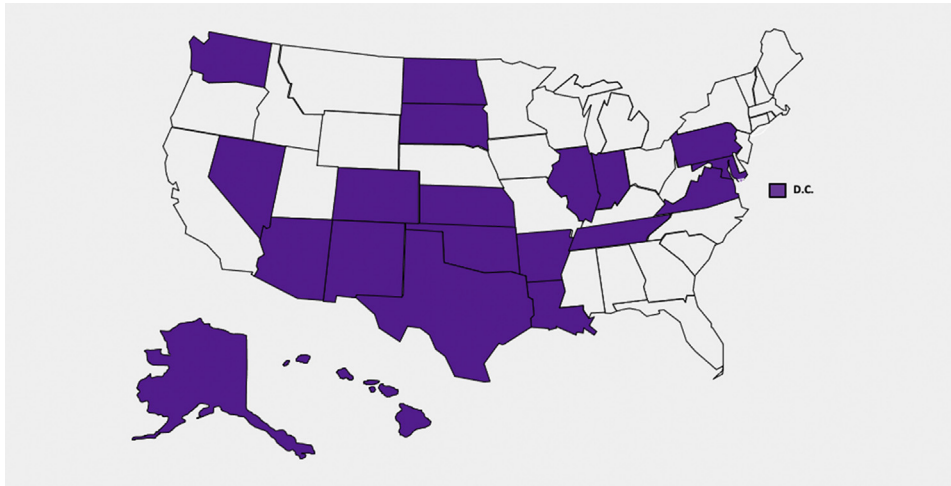


Figure 1. States represented in the listening sessions, September–November 2020.

platforms, and profiles were surveyed to assess conversations, with less attention to antivaccine content. Key words used to find appropriate conversations included #covid, #covid19, #vaccine, #fda, and #covidvaccine, as well as combinations of hashtags and key words. Considerations included review of these platform policies to monitor or restrict misleading or negative content regarding COVID-19 vaccines.

Listening sessions

The FDA Foundation, working with an outside expert (Chrisanne Wilks, PhD) and several organizations across the United States, organized 14 listening sessions from September to November 2020, hearing from 231 people in different states (Figure 1). The populations of focus, traditionally underrepresented communities and essential workers (including health care and retail), were selected in consultation with FDA. One session was conducted in Spanish. We worked with several academic and health care institutions, community and social service organizations, and employers to recruit participants.

Each session had a single moderator provided either by the collaborating organization or by the FDA Foundation. To assist in standardizing the session format and questions, a moderator's guide was developed before the scheduling of listening sessions. The guide set out the ground rules for the discussion and contained structured questions used by the moderator throughout the session. The sessions were designed to preserve as much confidentiality as possible, although in many cases, several session participants knew each other. Participants were not paid. On the basis of a recommendation from the collaborating organizations, participants in some sessions were offered a modest gift card as a measure of appreciation. In each session, the moderator, after explaining the purpose and format of the session, cycled through a series of prepared, open-ended questions about participant perspectives, concerns, motivators, and trusted sources regarding COVID-19 vaccine(s). Participants were asked to respond verbally with their views or type responses in the chat if they preferred (virtual sessions only). To the extent possible, moderators took steps to reduce bias by remaining neutral and objective

throughout the discussion, that is, no opinions were offered nor any attempt to correct misinformation. We conducted 10 sessions using videoconferencing technology and 4 in-person (in accordance with then-current physical distancing and mask-wearing recommendations). Each session took approximately 60 minutes. Table 1 shows the list of participant groups across sessions.

Message development

On the basis of the outcomes of the listening process, we developed a set of initial messages and a proposed list of messengers. On the basis of the themes that emerged during the listening sessions, we worked with health communication experts at a communications firm (Hamilton Place Strategies) to develop 10 initial messages that responded to the concerns expressed in the listening sessions. In addition, we developed a list of potential messengers on the basis of what we heard in the listening sessions and traditional sources for health information.

Message testing

Working with our communications firm, we tested these messages and messengers in a poll of 1001 registered voters through a national online omnibus survey. Respondents were provided a small remuneration for taking the omnibus survey.

The participants in the online survey were asked 2 questions:

- (1) How convincing do you find the following messages (Table 2 of Original Messages As Tested)? Respondents could select from 4 choices: very convincing, somewhat convincing, somewhat unconvincing, or very unconvincing.
- (2) How much trust do you have in the following people (Figure 2) to give you reliable information about a COVID-19 vaccine? Respondents could select from 4 choices: lot of trust, some trust, very little trust, or no trust.

Table 1
Participants groups across sessions

African American/black men and women in a Southern urban area
Black and Latinx community leaders in a Midwest urban area
English as second language/Latinx families and individuals in a mid-Atlantic suburban area
Indigenous/Native people from 11 tribes and villages
Indigenous/Native people providing social services to 400 tribes and villages
Clinical staff such as medical technicians, nurses, nursing assistants, orderlies, and physicians
Nonclinical staff in food service, IT, and custodial roles
Community and public health leaders of color in underserved communities
Hourly sales associates at retail stores in rural and urban settings
Midlevel managers of retail stores

Abbreviation used: IT, information technology.

Separately, the messages and messengers were tested in interviews with 41 experts in health care, health communications, and representative population groups, in surveys of members of 2 different professional associations, and in 1 English-as-a-second-language group. These interactions, which helped us refine messages, added depth to our survey findings so that we better understood interpretation and meaning in the messaging (rather than simple quantitative data).

Results

Review of traditional and social media

Overall, the reasons behind COVID-19 vaccine hesitancy are complicated, and specific to different groups, ruling out any global messaging as an effective communications strategy. Instead, the review of media (H Cobb, unpublished data, 2020) showed that any approach must be tailored to key populations. The initial analysis pointed to 4 main concerns among our focused audiences (traditionally underrepresented communities and frontline workers) regarding a potential COVID-19 vaccine: (1) a perceived lack of vaccine safety given the rapid development process; (2) misinformation or lack of information on vaccines, especially one for COVID-19, and in the vaccine development process; (3) distrust in the American government and its health care systems; and (4) impact of politics on the vaccine process and division on the basis of political persuasion. Those concerns were used to develop the initial questions for the participants in the listening sessions.

Listening sessions

As the participants in the listening sessions gave a variety of answers to the moderator's open-ended questions, their responses were grouped into primary and secondary themes. The primary themes were defined as ideas or concerns raised by multiple participants in more than 7 of the listening sessions. The secondary themes were defined as ideas or concerns raised by multiple people in fewer than 7 listening sessions or raised by a consistent minority in more than 7 of the listening sessions. The responses to the moderator's questions were at times powerful and insightful. Table 3 provides a sampling of actual participant quotes to questions. The perceptions and

concerns expressed reflect the time frame when the sessions were conducted, September 15–November 15, 2020 (C Wilks, unpublished data, 2020).

Primary themes

A primary theme was distrust in the COVID-19 vaccine development and review process, fueled by inconsistent information. Many participants expressed concern regarding what information to believe. All participants noted how the lack of credible and accurate information was a major obstacle in choosing to receive a COVID-19 vaccine, when available. The participants identified politics, social media, misinformation, and the newness of COVID-19 for the lack of credible information. Available information about the vaccine was viewed as confusing, overwhelming, and contradictory. The participants varied in what information they wanted to hear, including about adverse effects, adequate explanation of the development process, and addressing various myths and theories.

A related concern was the fear that the vaccine will not work for themselves and their family because the vaccine was not tested adequately in their particular subpopulation. Most participants were reluctant to be first in line to receive a vaccine. Many expressed a “wait-and-see” or “you-first” approach, preferring to monitor the results of the vaccines on others before considering the vaccine for themselves (with timelines from 2 months to 30 years).

Another strong concern was the worry that economics and politics were being prioritized over science and public health. People worried that politicians were interfering in vaccine development for political gain. Many felt that the speed of development meant that potential vaccines would not be adequately studied for safety, effectiveness, and adverse effects. Some felt that the speed of the process reflected a politicization of the review process or that companies were speeding development to enhance their profits. For example, the participants intimated that manufacturers might skip steps in the development process or oversight agencies might adjust the review process to meet deadlines imposed by political leaders. Participants assumed that vaccines influenced by desire for political gain or increased profit would be less effective and safe than those made with a focus on science and public health.

A final primary theme was the lack of trust in government, especially among people of color. Some people of color worried that the health system will treat them like “guinea pigs.” These concerns are rooted in past experiences, for example, Tuskegee.³ Some participants reported a loss of trust in leaders and groups that should have been providing clear, unbiased information on COVID-19 vaccines. Examples of institutions for which they lost trust included the Centers for Disease Control and Prevention (CDC) and FDA. Overall, participants reported limited trust in elected or appointed officials but higher trust in long-serving public servants.

Secondary themes

Secondary themes included the possible cost of, and access to, a vaccine, especially among certain populations or people in geographic regions that would perhaps have lower priority, for example, rural or remote areas, Indian reservations. Some

Table 2
Original messages as tested

Only safe and effective COVID-19 vaccines that make it through the rigorous, 3-phased testing process will be available.
COVID-19 vaccines are following the same rigorous, 3-phased testing process as every other vaccine.
COVID-19 vaccine development is moving faster than normal because our top medical experts have made it their highest priority, not because steps in the testing process are being skipped.
FDA will share information about approved COVID-19 vaccines so you can see the scientific evidence for yourself.
COVID-19 vaccine developers are trying to make sure their clinical trials reflect the nation's diversity because these vaccines must be proven safe and effective for everyone.
Medical experts and career public health officials, not politicians or their appointees, will decide when a COVID-19 vaccine is safe, effective, and ready for FDA approval.
Your health professional is a trustworthy source of information about a COVID-19 vaccine.
If you don't get a COVID-19 vaccine, you risk spreading the deadly virus to your loved ones and prolonging the pandemic.
The sooner you get a COVID-19 vaccine, the sooner your work, school, and social life can return to normal.
By getting a COVID-19 vaccine, you are protecting your child, parents, grandparents, or other loved ones.

Abbreviations used: COVID-19, coronavirus disease; FDA, Food and Drug Administration.

were concerned that some groups would receive access to better vaccines, whereas other groups (uninsured, poor, working class) would be provided access to lower quality vaccines.

A consistent minority of participants were concerned about government mandates for the vaccination of adults or children, with penalties for not complying. Health care personnel were not as resistant to employer mandates for vaccination,

perhaps because mandates were more common in their sectors. Overall, government mandates were viewed more negatively than employer mandates.

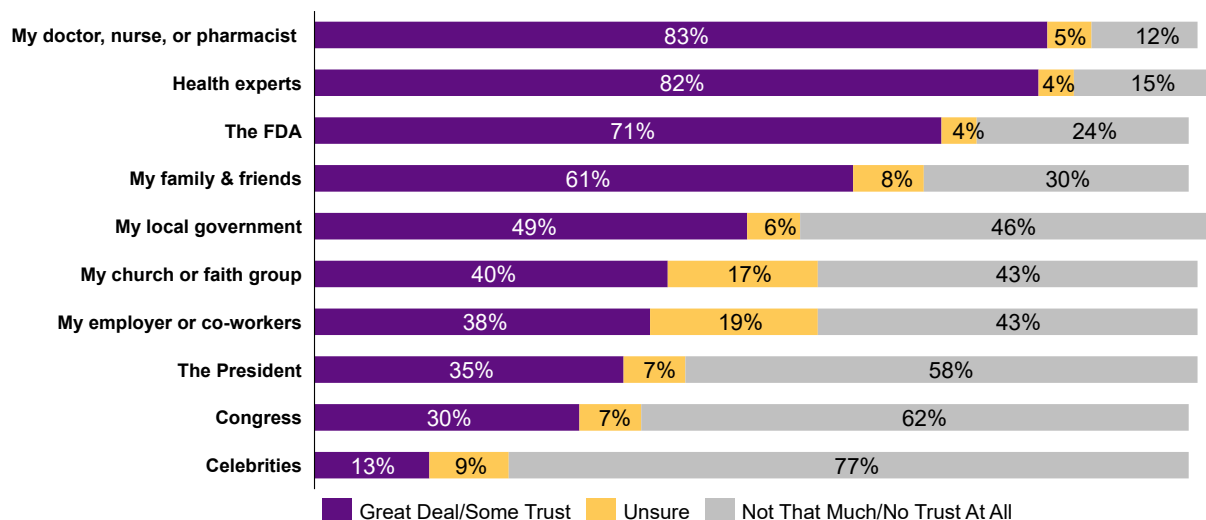
Some community health workers and frontline retail employees were concerned that a focus on vaccination would lead to less dependence and focus on other preventive behaviors such as mask-wearing and social distancing or on therapeutics and cures.

Other participants' views on a COVID-19 vaccine were affected by personal experience with vaccinations in the past. An adverse reaction for themselves or a family member made them wary of receiving a COVID-19 vaccine.

At least 1 participant in 13 of 14 listening session groups expressed a willingness to receive the vaccine as soon as it is available. Health care workers were generally more willing than other groups, in part because of a greater confidence in vaccinations, or wanting to be a role model for others. Frontline retail and health care workers also cited the desire to protect family members. Among racial and ethnic groups, Native Americans expressed greater interest in considering the vaccine. For those willing to take the vaccine when available, the desire to return to normal life and pandemic fatigue were primary reasons.

For communities of color, concerns about historic racism and persistent racial disparities in the health care system were strong and consistent undercurrents. African Americans and Native Americans viewed the vaccine development process through the lenses of historical and current racism in health care and public policy. Participants cited exploitation of their communities for the benefit of other population groups. Others noted the current and historical health disparities and lack of equity in health care. As a result, they were wary of being "experimented on" in vaccine trials or being among the

Various medical professionals and experts were the three most-trusted types of messengers to respond to concerns. Federal elected officials and high-profile celebrities were near the bottom.



N=1001, Registered Voters in the Likely Electorate, Nationally, November 16 - 20, 2020. Percentages are rounded and may not add up to 100.

Figure 2. Survey results of trusted messengers. Abbreviation used: FDA, Food and Drug Administration.

Table 3
Actual participant quotes

Fear that the vaccine will not work for me or my community
“I need to know that all the minorities who took it are okay. I need to know it works for everybody. I am not trying to be harmed.”
“Indian people are different biologically but then who constitutes as Indian – half Indian?”
“Unless there is a specific study done with us and our specific make-up, we are going to be incidentally immune with a vaccine that is studied with a proportionally lower number of participants in the study group.”
Distrust of government
“Who can we trust? That’s the million-dollar question.”
“I also hear so many people arguing about the pros and the cons. Mostly cons because of distrust of the government from past experience.”
“When COVID first came out, I trusted the CDC website and was sharing from there. Now I trust the FDA and CDC much less than I did when this first came out.”
“I don’t think the FDA can be trusted to keep people safe.”
“When I hear the FDA say they have a particular process, but then I hear the White House say they can cut that in half or negate it – it brings more distrust.”
Concern about the speed of the process
“The speed is appreciated, but there are questions.”
“They want to get one out as soon as possible. Which I don’t think is very safe.”
“We all know how long vaccines take, so to hear that it will be ready in a few months is concerning.”
“I would not be first in line and I would want to see some data.”
“Vaccines takes years to develop and test. For them to try to do it in a year is pretty absurd.”

Abbreviations used: COVID, coronavirus disease; CDC, Centers for Disease Control and Prevention; FDA, Food and Drug Administration.

first to take the vaccine, once available, viewing this situation as an unofficial extension of clinical trials.

The participants were asked, again in an open-ended fashion, what factors would increase their willingness to receive the vaccine. Overall, the main factor was receiving clear and transparent information. Finally, the participants were asked, without prompting, who they viewed as trusted sources, with clinicians, particularly those known to them personally, topping the list. Other trusted sources mentioned by participants in the listening sessions included independent researchers and scientists, God, and international sources, for example, World Health Organization and other countries’ governments.

After hearing their open-ended responses, the moderator asked the participants to react specifically to the following: Federal government agencies (CDC, FDA), state and local governments, and long-standing public servants. Results were mixed with negative, positive or neutral views expressed; often their concerns were based on recent statements or decisions that appeared to politicize the development process.

Those who did not engender trust included any person or organization with a perceived conflict of interest. This included pharmaceutical companies and those working in or allied with the pharmaceutical industry. Different groups reacted differently to different types of messengers. For example, in the African American groups, some celebrities were perceived to have possible conflicts of interest. A list of the trusted messengers as expressed differentiated by the different communities can be found in [Table 4](#).

Message development

On the basis of the results of the listening sessions, an initial list of messages was developed (Hamilton Place Strategies, Unpublished; 2020) along with a list of potential messengers and venues, for example, social media, physician’s office, or church. The messages were written to be tailored to specific situations, for example, health care worker speaking to a patient or in an education or outreach activity. One of the outcomes of the message development phase was a determination to develop a set of infographics to illustrate message themes. These figures are designed primarily with pharmacists, physicians, and other health professionals in mind to provide them with a visual aid to explain the vaccine development process and how it was accelerated without sacrificing safety or effectiveness ([Appendices 1 and 2](#)).

Message testing

The messages all tested in a narrow range. In the poll of registered voters, there was only an 8-point difference between the best performing message (72% found the message convincing) and worst performing message (64% found the message convincing). Subsequently, we tested the messages in meetings with various individuals representing a range of health and communication expertise. On the basis of their feedback, we continued to refine the messages. See [Table 5](#) for the top-performing and revised Messages.

In contrast to the messages, survey respondents expressed distinct preferences in who they considered to be credible messengers, with personal health professionals such as pharmacists and physicians ranking the highest and celebrities ranking lowest ([Figure 2](#)).

Discussion

This project was conducted in a 3.5-month period within a tumultuous year of societal and political unrest. The listening sessions were conducted both before and after the presidential election and amid communal discussions and action to correct racial and ethnic disparities. People’s concerns will continue to evolve with changes in political leadership, as efforts to address inequalities continue and as greater numbers of people, including friends and family, are vaccinated.

Messages about the FDA process are critical to building public trust and understanding around the safety and efficacy of COVID-19 vaccines. FDA Center for Biologics Evaluation and Research (CBER’s) active engagement in this project has helped, and will continue to help, shape their own communications.

Sharing the messages will be best done through local, regional, and national vaccination outreach campaigns and through informed one-on-one interactions in trusted community settings. On the basis of what we learned through the listening session and the message testing process, the FDA Foundation developed recommendations for public health experts to use when encouraging Americans to receive the vaccine.

One of the questions asked in the listening sessions was, “Who would you trust and who do you find credible?” We heard that the most credible sources of information were the people around them, those who were familiar and were trusted, those who had received the vaccine, their health

Table 4
Trusted messengers by group

Native Americans	African Americans	Latinx	Frontline workers
Tribal leaders and elders	Black health professionals who have taken the vaccine	Personal health care providers	FDA
American Indian higher education consortium	Family and friends who have taken the vaccine	Anthony Fauci, M.D., NIH/NIAID Director	Major hospitals
Johns Hopkins Center for American Indian Health	Churches and faith groups	Churches	Doctors and doctors' groups
Wes Studi, Native American film actor and producer	—	Friends and family	Familiar or local medical institutions

Abbreviations used: FDA, Food and Drug Administration; NIH/NIAID, National Institutes of Health/National Institute of Allergy and Infectious Diseases.

professionals, and their family members, particularly elders. The participants emphasized that messengers who are part of the community are important, as opposed to outside experts who came to speak with them and left soon afterward. In addition, hearing from others of their personal experience with COVID-19 helped shape their views.

The research also helped us fine-tune key word choices. For example, the word “rigorous” came up often in the expert consultations, therefore, we made sure to incorporate the word into the messages. Discussions with experts echoed the importance of the value of community and family heard initially in the listening sessions. Specific expert feedback provided insights into loaded words that helped guide the recommendations, either to include those concepts that strengthened the messages or to avoid those concepts that might distract from the message. What we heard in the listening sessions, what we learned from the experts, and how we applied best practices in health education helped shape the following recommendations.

Focus more on the messenger rather than on the message itself

Participants distinguished more between messengers, with some messengers being seen as more trustworthy, than in the messages themselves. Communicating through the best messenger is more important than prioritizing one of several strong messages.

Messengers should be used strategically. Generally, 2 categories of messengers were consistent across populations: (1) personal health professionals and health experts and (2) family, friends, and acquaintances. Pushing messages to the local or community level should be prioritized because of the consistent confidence reflected in personal health care providers; thus, these professionals need clear, credible information to answer questions and combat misinformation. Friends and family who share their motivation and experience receiving the vaccine can help alleviate fear and may persuade others.

When it comes to messengers, diversity in race and ethnicity is essential. Each group listed different messengers as trustworthy. Each type of messenger has their own strengths and should be enlisted strategically. Although not ranked highly in our polling regarding vaccine questions, celebrities can still be powerful messengers to help raise awareness and to model vaccine use.⁴ A public health campaign should recruit a diverse array of spokespeople, representing different demographics, to get the vaccine. These spokespeople can promote vaccine use through television, print, social, and other media.

“Show, don’t tell.” People want to see data and others receiving a vaccine

Simple statements that a vaccine is “safe and effective” are only partially successful, as the audience is forced to trust the messenger. Strengthening the statement with evidence or resources allows the audience to draw their own conclusions. Examples of these resources can be seen in [Appendices 1 and 2](#), which illustrate the typical vaccine development and review process and how time was saved in the COVID-19 vaccine process. These infographics were developed by the FDA Foundation in cooperation with FDA and disseminated to health professionals ([Supplementary Figures 1 and 2](#)).

Sample messages that “show” rather than merely “tell” include the following:

“Only safe and effective COVID-19 vaccines that have been rigorously tested on tens of thousands of volunteers will be approved.”

“COVID-19 vaccines are following the same rigorous, three-phased testing process as every other vaccine.”

“The FDA will publicly share information about COVID-19 vaccines so you can see the evidence for yourself.”

Tailor messages to the audience

The foundation of health communication is that “one message does not fit all.” Although our listening sessions made clear that consistent information on COVID-19 vaccines is essential, those messages need to be strategically personalized. One approach is to move the message from the abstract (“Vaccines can help stop the spread of COVID-19”) to the familiar (“Getting a vaccine can help protect your family”). The latter message is personalized (“your family”), makes an emotional link (“protect”), and speaks to action (“Getting a vaccine”). Using emotional connections can be tricky; we found that some audiences responded negatively to the use of shame or morality messaging. For some traditionally under-represented audiences, invoking the concept of duty to country or community did not increase likelihood of taking the vaccine and in some cases elicited a negative emotion.

Explain the process

Four of our top 5 performing messages addressed the vaccine development process—specifically, concerns about speed and safety. Key words, such as “rigorous” and “see the

Table 5
Top performing and revised messages

The FDA is publicly sharing information about COVID-19 vaccines so you can see the evidence for yourself.
Only safe and effective COVID-19 vaccines that have been rigorously tested on tens of thousands of volunteers will be approved.
Scientists and career public health officials, not politicians or their appointees, will decide when a COVID-19 vaccine is safe, effective, and ready for public use.
By getting a COVID-19 vaccine, you are protecting yourself, your children, parents, grandparents, and other loved ones.
COVID-19 vaccine development is moving faster than normal because the medical and scientific community have made it their highest priority, not because any steps have been skipped.

Abbreviations used: COVID-19, coronavirus disease 2019; FDA, Food and Drug Administration.

evidence for yourself,” were highlighted in expert interviews, whereas all testing showed that messages of reassurance (such as promising transparency and explaining that steps were not skipped) were critical. Messages about process need to be tailored to the audience. Keep it digestible and high-level for most groups with direction to additional resources for health care providers who are communicating with patients.

Meet people where they are

Although there were common themes across groups, nuances existed on the basis of culture, region, and role. A few examples are highlighted below:

- (1) *Health care workers* requested recommendations for children, people who are pregnant, or those testing positive for antibodies and sought information regarding what to expect between doses and what support would be available if they experienced adverse effects (medical care, sick leave).
- (2) *Community health workers* asked about safety of their vulnerable clientele, for example, older people, people with comorbidities, and other high-risk populations.
- (3) *Retail workers* expressed a desire for public adherence to prevention guidelines, such as handwashing and mask-wearing, while waiting for vaccine uptake.
- (4) *Native Americans, African Americans, Latinx* were concerned about safety specifically for their racial or ethnic subpopulations.

Acknowledge and address people's concerns and fears, such as fear of being exploited or concerns about the safety of the vaccine

Messengers should demonstrate their understanding and empathy of these concerns before pivoting to tested core messages. For example, we should proactively acknowledge systemic racism. People of color are in a particularly difficult place. They are concerned about the legacy of historic racism, which make them naturally skeptical, but also realize that historic racial disparities in health care, income, and housing make them especially vulnerable to the ravages of COVID-19.

A sample message could be “Recognizing the impact of historic injustices, vaccine developers are working to make

sure clinical trials reflect the nation's diversity. These vaccines must be proven safe and effective for everyone.”

Consistently repeat core themes

Most audiences will need to hear core messages multiple times from multiple, credible sources through multiple channels of communication. Repetition creates a positive feedback loop. A surround-sound of trusted messengers delivering the same credible messages will boost confidence and information levels.

Focus first on the “persuadables”

Over the course of 14 listening sessions, we could see that whereas a few participants would likely never take the vaccine, many others were hesitant, clearly wanting more information before making a decision. Many Americans want a COVID-19 vaccine, even if they want more information about its safety before agreeing to receive the vaccine. Approximately 64% of the respondents in our poll said they were “likely” to get a COVID-19 vaccine once approved.

Be ready to respond to vocal critics

There will always be those with ingrained concerns about any vaccine who are likely to be outspoken about their views. Effective communication takes into consideration that those who are vaccine-hesitant will hear this information and possibly become even more concerned, making it even more important that messages correct misinformation (including intentional falsehoods and conspiracy theories) to prevent confusion or unfounded concern.

Conclusion

After months of living with anxiety and uncertainty, as well as incalculable human and economic loss, we now have a light at the end of the tunnel with the authorizations and public availability of at least 3 COVID-19 vaccines (as of April 2021), providing the potential for herd immunity in the U.S. population. To achieve that goal, it is important that trusted messengers be equipped to address the concerns, and answer the questions, of those who express hesitancy to get the vaccine. This will help to ensure that Americans understand that vaccination will be an effective way to put an end to the COVID-19 pandemic. The recommendations that we developed through the findings from the listening session and the message testing can be leveraged by public health experts to encourage Americans to receive the vaccine.

However, efforts to address COVID-19 vaccine hesitancy should include ongoing attempts to engage the public, gather their questions, and provide responses effectively. As we learned from the listening sessions, Americans want reassurance that a vaccine is safe, but they also need to be engaged in a process that fosters trust and understanding. FDA will continue to disseminate these recommendations broadly to inform COVID-19 vaccine outreach efforts at the local, state, and national levels. Sharing clear, evidence-based information will not only help start the conversation about vaccines but will collectively move us to the point where we can end this pandemic.

Acknowledgments

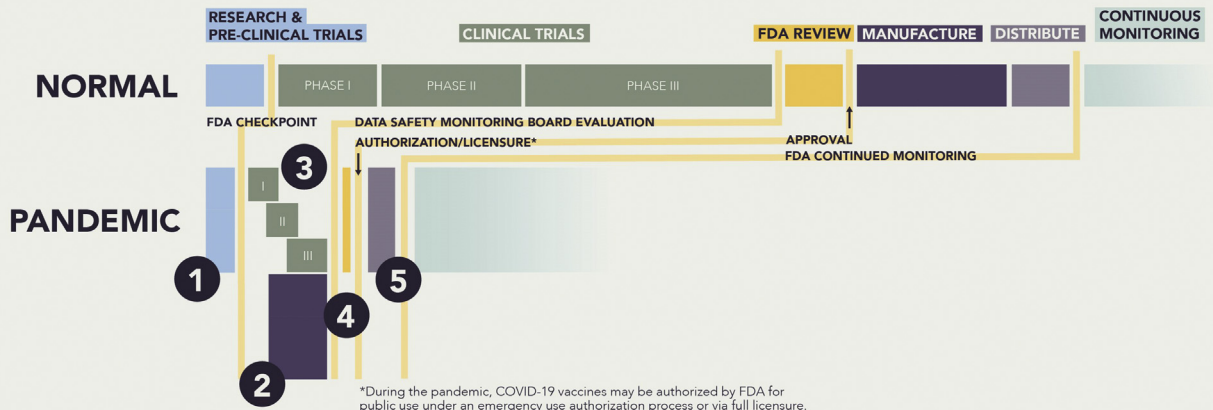
Many people helped to complete this project. Ms. Heather Cobb prepared the media analysis; Chrisanne Wilks, PhD, helped to organize, and prepared the analysis of, the listening sessions; and Hamilton Place Strategies drafted the initial messages and conducted the message testing. We acknowledge the many people and organizations who assisted with our listening sessions. Throughout this project, we worked closely with FDA CBER officials, namely Peter Marks, MD, PhD, Julia Tierney, JD, Julianne Vaillancourt, BSPharm, and Lorrie McNeil, sharing our findings, gaining their feedback, and facilitating real-time incorporation into their communications efforts.

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Appendix

Vaccine Development Process

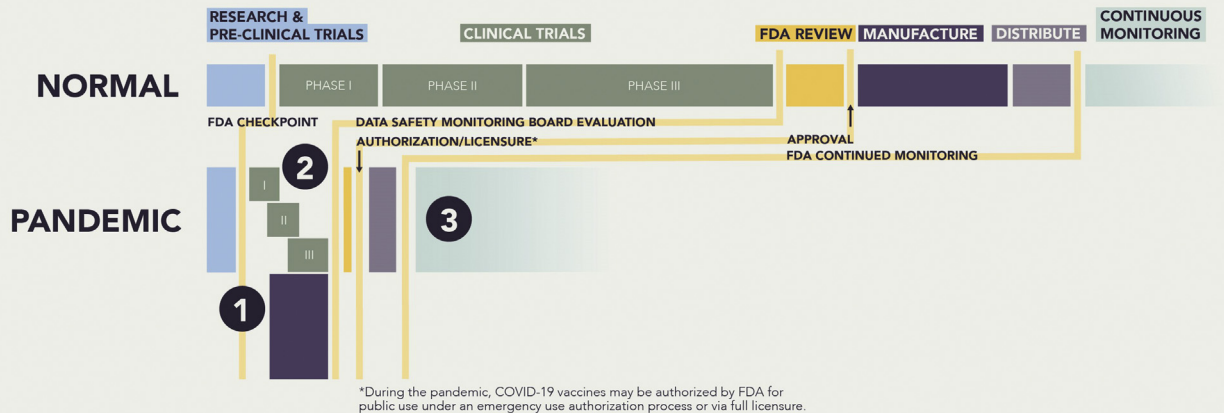


HOW WAS TIME SAVED?

- 1 RESEARCH**
The SARS-CoV-2 genetic sequence was identified and tested right away thanks to past research.
- 2 MANUFACTURE**
Private companies and the U.S. government are investing in manufacturing. FDA is inspecting facilities earlier (while clinical trials are ongoing), which allows product to be manufactured for rapid distribution upon authorization/approval instead of during FDA review, in normal circumstances.
- 3 CLINICAL TRIALS**
Clinical trials were carefully designed to test for safety, dosage, and effectiveness in phases that partially overlapped instead of running consecutively. Because COVID-19 is so widespread, finding people to participate in the clinical trials and assessing the vaccines' performance have been faster than normal.
- 4 LICENSE/AUTHORIZATION**
An Emergency Use Authorization can be requested by vaccine developers for FDA to review preliminary data from clinical trials to determine if the benefit outweighs the risks for use in a public health emergency. The vaccine data must show safety and efficacy to earn an emergency use authorization.
- 5 DISTRIBUTE**
Substantial U.S. government resources are being used to coordinate distribution to the public.

Supplementary Figure 1. Vaccine development process: How was time saved?

Vaccine Development Process



HOW DO WE KNOW IT'S SAFE AND EFFECTIVE?

- 1 SAFETY CHECKS**
 A COVID-19 vaccine needs to pass all the same safety requirements as a typical vaccine. After a safety review by FDA at the initial checkpoint determines no issues, each COVID-19 vaccine is allowed to be studied in humans for the first time in a Phase I trial.
- 2 CLINICAL TRIALS**
 The large number of volunteers in each COVID-19 vaccine phase III study made it easier to identify possible side effects and assess how well the vaccine prevents COVID-19.
- 3 MONITORING**
 The FDA monitors for long-term effects and safety of a vaccine during and after its distribution.

Phase I
20 to 100 people

Phase II
Hundreds of people

Phase III
Tens of thousands of people

In the first two vaccine applications (from Pfizer and Moderna), Phase III included 30,000+ people (thirty times the amount shown) and 30% to 40% of volunteers are from racial and ethnic minorities.

Supplementary Figure 2. Vaccine development process: How do we know it's safe and effective?